

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE**

**IN RE: VALSARTAN, LOSARTAN,
AND IRBESARTAN PRODUCTS
LIABILITY LITIGATION**

This Document Relates to All Actions

MDL No. 2875

Honorable Robert B. Kugler,
District Court Judge

Oral Argument Requested

**REPLY IN SUPPORT OF DEFENDANTS'
JOINT MOTION TO STAY PROCEEDINGS PENDING APPEAL
PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 23(f)**

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INTRODUCTION

Plaintiffs concede in their opposition that notice should not be disseminated pending a ruling on defendants' Rule 23(f) petitions. Although they also argue that other class-related activities should continue, their arguments all fail.

First, defendants have established a likelihood of succeeding on their appeal. Plaintiffs argue in response that the petitions raise “run-of-the-mill issues” that are ill-suited for Rule 23(f) review. (Pls.’ Opp’n at 12-13.) But there is nothing “run-of-the-mill” about defendants’ appeal, which involves four separate 23(f) petitions challenging scores of medical monitoring, consumer and TPP subclasses that even this Court recognized would be “onerous and [require] a steep climb of effort” to try. (Order at 24 ([ECF No. 2261](#))).) Although this Court determined that certification of these classes was proper, there is a reasonable possibility that the Third Circuit will disagree, which satisfies the requisite likelihood of success for a motion to stay.

Second, plaintiffs argue that defendants would not be irreparably harmed by proceeding with litigation while the petition is pending because pretrial activities would be necessary regardless of how the Third Circuit rules. But the scope of that work (especially with respect to damages) hinges on whether plaintiffs’ claims proceed on a class or individual basis. Moreover, plaintiffs have not even attempted to outline the scope of the trial they insist the parties continue working

up, which would make it impossible for either side to engage in meaningful discovery, much less properly and coherently draft and oppose dispositive motions.

Third, plaintiffs complain that a brief delay of class-related litigation would unfairly prejudice them and the absent class members. But plaintiffs have delayed disposition of defendants’ 23(f) petitions by seeking and obtaining a two-week extension for responding to those petitions, which might otherwise have been ruled on by the end of the month.

Fourth, plaintiffs argue that a stay would not be in the public interest because defendants do not have a basis for appealing the class certification ruling—but that is not the relevant standard, and is, in any event, wrong for the reasons discussed above.

ARGUMENT

I. DEFENDANTS ARE LIKELY TO SUCCEED ON THE MERITS.

As explained in defendants’ opening brief, a stay is proper during the pendency of defendants’ Rule 23(f) petitions because there is a strong likelihood that the Third Circuit will grant defendants’ Rule 23(f) petitions and ultimately reverse the class certification order. (*See* Defs.’ Mem. at 4-9.) Plaintiffs’ arguments in response lack merit.

First, plaintiffs argue that “[i]t is far from *certain* that the Third Circuit will grant” the petitions. (Pls.’ Opp’n at 6 (emphasis added).) But certainty is not the

standard; rather, the movant need only establish “the possibility that defendant’s appeal may be accepted for discretionary review.” *Dujanovic v.*

MortgageAmerica, Inc., No. CV98-TMP-0235-S, 1999 U.S. Dist. LEXIS 17231, at *2-3 (N.D. Ala. Apr. 21, 1999) (granting motion to stay because “the significant trend going against the path chosen here makes real the possibility that defendant’s appeal may be accepted for discretionary review and that it may prevail”).

Defendants have more than satisfied that standard because the Third Circuit grants review more “liberal[ly]” than “other circuits” and will do so on a number of grounds, *Laudato v. EQT Corp.*, 23 F.4th 256, 260 (3d Cir. 2022)—***all of which are met in this case.***

Unprecedented and erroneous class certification determination. Plaintiffs argue that “there is nothing ‘unprecedented’ about the Court’s class certification ruling” because the Third Circuit has endorsed the use of “subclasses as necessary.” (Pls.’ Opp’n at 7 (citing *Grandalski v. Quest Diagnostics Inc.*, 767 F.3d 175, 183 (3d Cir. 2014)).) But in *Grandalski*, the Third Circuit not only affirmed the ***denial*** of a nationwide consumer-fraud and unjust-enrichment class action; it also “explicitly recognized that plaintiffs face a significant burden to demonstrate that grouping is a workable solution.” 767 F.3d at 183. As another court of appeals recently explained, “[s]ublcass’ is not a magic word that remedies defects of predominance,” a principle so rudimentary that it led the Fifth Circuit to

affirm the striking of class allegations at the pleading stage. *Elson v. Black*, 56 F.4th 1002, 1007-08 (5th Cir. 2023). That same logic applies here because even if the groupings adopted by this Court accurately reflected the relevant state laws, there would still be 111 legal variations to consider in a single consumer and TPP proceeding—more than double the amount deemed unfeasible by *Grandalski* and *Elson*. See, e.g., *Grandalski*, 767 F.3d at 183-84; *Elson*, 56 F.4th at 1006-07.

Even the Court itself acknowledged that a trial of so many disparate legal frameworks may be “onerous and [require] a steep climb of effort,” before reasoning that its “experience with the MDL weighs toward certification” (Order at 24), a principle that has never been countenanced by the Third Circuit and has been rejected by other circuit courts. See *In re Nat’l Prescription Opiate Litig.*, 976 F.3d 664, 670, 673 (6th Cir. 2020) (reversing certification of negotiation class, which was “designed to fundamentally alter the nature of the MDL—to foster settlement through a novel means of class action”). Accordingly, the number and complexity of the subclasses and the Court’s reasoning are all unprecedented.

Development of class action law. Plaintiffs argue that the Third Circuit may not grant the petitions because the law governing the certifiability of medical monitoring classes “has been well-settled” in this circuit and, thus, immediate review would not facilitate the development of class certification law. (Pls.’ Opp’n at 8.) This argument is backwards. If the law governing medical monitoring is

“well-settled,” then the medical monitoring classes should not have been certified in the first place. After all, the Third Circuit has repeatedly rejected single-state medical monitoring classes, going so far as to question whether “the necessity for individuals’ medical monitoring regimes can” *ever* “be proven on a class basis.”

Gates v. Rohm & Haas Co., 655 F.3d 255, 268 (3d Cir. 2011); *Barnes v. Am.*

Tobacco Co., 161 F.3d 127, 146 (3d Cir. 1998) (“Although the general public’s monitoring program can be proved on a classwide basis, an individual’s

monitoring program by definition cannot.”).¹ Moreover, “no circuit court of appeals has ever approved certification of a medical monitoring class action.”

Coleman v. Union Carbide Corp., No. 2:11-0366, 2013 U.S. Dist. LEXIS 140613, at *119-120 (S.D. W. Va. Sept. 30, 2013) (relying on *Gates*). Accordingly, the Third Circuit is very likely to grant the petitions precisely because the ruling

¹ Although plaintiffs assert that courts have certified medical monitoring classes notwithstanding *Gates* and *Barnes* (see Pls.’ Opp’n at 9), one of those cases—*In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prods. Liab. Litig.*, No. 98-20626, 1999 WL 673066 (E.D. Pa. Aug. 26, 1999)—predated *Gates* and has been widely criticized, see *In re Fosamax Prods. Liab. Litig.*, 248 F.R.D. 389, 396 & n.8 (S.D.N.Y. 2008) (noting that *Diet Drugs* was an “exception[]” to the “almost unanimous[]” rejection of medical monitoring classes), while the other case—*Baker v. Sorin Grp. Deutschland GMBH*, No. 1:16-cv-00260, 2017 U.S. Dist. LEXIS 235430 (M.D. Pa. Oct. 23, 2017)—involved uniform classwide exposure and few (if any) alternative risk factors such that the CDC had sent out “notices that suggest[ed] that *all* patients exposed” to the product “receive medical monitoring,” *Baker*, 2017 U.S. Dist. LEXIS 235430, at *32 (emphasis added).

threatens to change the law governing medical monitoring class actions both inside and outside this circuit.

Settlement pressure. Plaintiffs also argue that the class certification ruling does not place “inordinate settlement pressure” on defendants, contending that the Court’s single reference to a “Class Action settlement” in the decision is distinguishable from the situation in *Laudato*, where the district court “repeatedly . . . hinted at the consequences of not playing along.” (Pls.’ Opp’n at 10 (quoting *Laudato*, 23 F.4th at 261).) But there can be no question that this Court has repeatedly sought to “nudge [the parties] toward[] settlement,” *Laudato*, 23 F.4th at 261, including mandating the retention of separate settlement counsel (over defendants’ objections) ([ECF No. 1821](#)), and repeatedly expressing a desire for a global resolution of the valsartan litigation. (*See, e.g.*, 3/27/2019 Hr’g Tr. 29:13-30:8 ([ECF No. 77](#)); 2/28/2022 Hr’g Tr. 43:2-13 ([ECF No. 1946](#)).) In short, any one of these grounds justifies 23(f) review; taken together, they establish a very high likelihood that defendants’ petitions will be granted.²

² Plaintiffs highlight a 2014 study indicating that the percentage of 23(f) appeals granted by the Third Circuit dropped from 86 percent in October 31, 2006 to 35.8 percent in December 31, 2013. (*See* Pls.’ Opp’n at 6 & n.2 (citing John H. Beisner et al., *Study Reveals US Courts of Appeal Are Less Receptive to Reviewing Class Certification Rulings* (Apr. 29, 2014)).) But that study found that, even with the decline, the Third Circuit was “[t]he second most receptive Rule 23(f) jurisdiction.” Beisner, *supra*.

Second, plaintiffs also argue that defendants have not demonstrated that the Third Circuit is likely to reverse the class certification ruling. (See Pls.’ Opp’n at 11.) As just discussed, however, the Court of Appeals (including in authority cited by plaintiffs) has repeatedly rejected medical monitoring and economic-loss class actions involving far fewer subclasses, legal permutations and factual variations than those present here. As a result, there is a significant likelihood that the Third Circuit will conclude that the class certification order should be reversed.

In any event, as explained in defendants’ opening brief, the relevant standard is “not that [the petitioning party] will win on the merits,” *Brown v. Wal-Mart Stores, Inc.*, No. 5:09-CV-03339-EJD, 2012 WL 5818300, at *2 (N.D. Cal. Nov. 15, 2012) (cited in Defs.’ Mem. at 7); otherwise, motions to stay would never be granted because the court that granted class certification necessarily thinks that decision is correct. See *Salhotra v. Simpson Strong-Tie Co.*, No. 19-cv-07901-TSH, 2022 U.S. Dist. LEXIS 67493, at *4-6 (N.D. Cal. Apr. 12, 2022) (noting that “[e]valuating Plaintiffs’ likelihood of success on appeal places the Court in the uncomfortable position of reviewing the merits of its own order, which of course the Court thinks is correct,” but nonetheless granting motion to stay). Instead, the movant satisfies this prong by raising “serious legal questions.” *Brown*, 2012 WL 5818300, at *2 (citation omitted). Although plaintiffs contend that the questions presented in defendants’ cases involved “unsettled question[s] of law” (Pls.’ Opp’n

at 11-12 (citation omitted)) somehow rendering those cases inapposite, arguments like those in the petitions are *even more serious* than ones of first impression because they implicate binding appellate precedent that a district court cannot disregard.³

In short, the petitions raise important questions about class certification, and defendants respectfully believe that reversal is likely because the certification order is contrary to Third Circuit precedent.

II. DEFENDANTS WILL BE IRREPARABLY HARMED ABSENT A STAY.

As explained in defendants’ opening brief, if the proceedings continue on their current course, defendants will be irreparably harmed because they will be forced to expend significant and potentially unnecessary time and expense on activities related to discovery, expert work and dispositive motion practice and class notice. (*See* Defs.’ Mem. at 9-15.) In response, plaintiffs concede that “deadlines regarding class certification notice and the opt out period should be put

³ By contrast, the cases cited by plaintiffs are, in fact, inapposite. The first, *Johnson v. Geico Cas. Co.*, 269 F.R.D. 406, 412-13 (D. Del. 2010), involved classes that were later decertified, *see Johnson v. Geico Cas. Co.*, 672 F. App’x 150, 157 (3d Cir. 2016), highlighting why stays would have been appropriate in those matters; and in the second case, *Huffman v. Prudential Ins. Co. of Am.*, No. 2:10-cv-05135, 2018 WL 1281901, at *2 (E.D. Pa. Mar. 12, 2018), the court denied the motion to stay in light of “the Eleventh Circuit’s recent decision not to grant the Rule 23(f) petition” in a “factually similar” case, *Huffman*, 2018 WL 1281901, at *2.

on hold,” but insist that the “work needed to set the groundwork for notice should proceed.” (Pls.’ Opp’n at 4.) But plaintiffs do not elaborate on what they mean by “groundwork for notice,” which presumably would entail devising the notice, litigating the adequacy of such notice, and perhaps even identifying potential class members, “requir[ing] a great deal of time and effort—time and effort that would possibly be expended in vain should the [Third Circuit] grant [defendants’] petition.” *Fernandez v. RentGrow, Inc.*, No. JKB-19-1190, 2022 WL 1782641, at *4 (D. Md. May 31, 2022) (rejecting alternative request to stay dissemination of notice but allow preparations for the issuance of that notice).

Plaintiffs also argue that a “waste of resources is not irreparable harm unless the amount of loss would be so significant as to force the moving party out of business entirely.” (Pls.’ Opp’n at 14 (citing *Minard Run Oil Co. v. U.S. Forest Serv.*, 670 F.3d 236, 255 (3d Cir. 2011)).) But plaintiffs fundamentally misread *Minard*—which merely reiterated that “a purely economic injury, ***compensable in money***, cannot satisfy the irreparable injury requirement” of a preliminary injunction. *Minard*, 670 F.3d at 255 (emphasis added) (quoting *Frank’s GMC Truck Ctr., Inc. v. Gen. Motors Corp.*, 847 F.2d 100, 102 (3d Cir. 1988)); *see also Frank’s*, 847 F.2d at 102-03 (“The availability of adequate monetary damages belies a claim of irreparable injury.”). Here, defendants could not recoup the substantial litigation-related costs that they would incur absent a stay. *See*

Nieberding v. Barrette Outdoor Living, Inc., No. 12-2353-DDC-TJJ, 2014 U.S. Dist. LEXIS 159021, at *11-12 (D. Kan. Nov. 10, 2014) (staying discovery pending 23(f) review because “[m]onetary losses that are not recoverable can constitute irreparable harm”).

To the extent plaintiffs do cite caselaw that they claim has rejected “[m]ere litigation expense” as irreparable injury in the context of a motion to stay pending Rule 23(f) review (Pls.’ Opp’n at 14 (citation omitted)), that authority either confirms that “wasteful[] [and] unrecoverable . . . costs *are* proper considerations,” *Ewing Indus. Corp. v. Bob Wines Nursery, Inc.*, No. 3:13-cv-931-J-39JBT, 2015 WL 12979096, at *3 (M.D. Fla. Feb. 5, 2015) (emphasis added), or rejected claims of potentially unnecessary discovery expenses that pale in comparison to the costs the parties would have to bear in working up the kind of mammoth consumer and TPP trial contemplated by the class certification ruling, *see Heinzl v. Cracker Barrel Old Country Store, Inc.*, No. 2:14-cv-1455, 2016 WL 5107173, at *2 (W.D. Pa. June 8, 2016) (cited in Pls.’ Opp’n at 14) (rejecting claim of irreparable injury due to discovery costs in putative injunctive-relief-only class action under the Americans with Disabilities Act involving just one defendant and one plaintiff).⁴

⁴ Plaintiffs assert that defendants’ cases “only found irreparable harm . . . because at least one issue on appeal would likely resolve the entire case.” (Pls.’ Opp’n at 16.) But plaintiffs only address two of those cases, one of which did not turn on that fact, *see In re Lorazepam & Clorazepate Antitrust Litig.*, 208 F.R.D. 1, (cont’d)

Plaintiffs also argue that working up the previously planned individual TPP trial would not be wasteful because the remaining discovery “will be necessary regardless of the Third Circuit’s determinations.” (Pls.’ Opp’n at 15.) But that is illogical since the scope of that discovery (especially with regard to damages) will turn on the outcome of defendants’ petitions. *See Hudock v. LG Elecs. U.S.A., Inc.*, No. 16-1220 (JRT/KMM), 2020 WL 5849204, at *1 (D. Minn. Oct. 1, 2020) (granting defendants’ stay motion “[b]ecause the Eighth Circuit’s decision may affect the need for additional class-wide discovery”). In particular, classwide damages cannot be ascertained until the parties know who is opting out—a step plaintiffs *agree* cannot happen until the Third Circuit resolves defendants’ petitions. And any additional work that the parties undertake with respect to classwide discovery and damages would be a complete waste of time if the Court’s class certification decision is reversed by the Third Circuit.

Finally, plaintiffs have not provided any details on the scope of the trial that they expect the parties to work up while the Third Circuit considers defendants’ petitions. Although plaintiffs vaguely assert that the trial “likely [would] not”

6 (D.D.C. 2002) (granting stay where the “the [certification issue] could substantially reshape” the case), and the other of which did not involve an appeal that could terminate the entire case, *see Cruson v. Jackson Nat’l Life Ins. Co.*, No. 4:16-CV-00912, 2018 WL 2937471, at *5 (E.D. Tex. June 12, 2018) (granting stay notwithstanding that “individual breach of contract claims against Jackson will still exist” even if certification decision were reversed).

encompass “all classes and subclasses” (Pls.’ Opp’n at 15), they do not identify *which* of those classes and subclasses they do intend to try, much less specify what claims and state laws are implicated by their as-yet-unidentified proposal. These are not minor details; rather, they are critical to preparing and opposing dispositive motions and motions in limine and otherwise working up the previously planned trial. In short, plaintiffs’ opposition only highlights why proceeding with class-wide discovery, dispositive motion practice and trial preparations during the pendency of the 23(f) petitions would be expensive, likely wasteful and ultimately impracticable.⁵

III. A STAY WILL NOT PREJUDICE OR HARM PLAINTIFFS.

Plaintiffs also complain that a stay will unfairly “delay final resolution” of their claims. (Pls.’ Opp’n at 17.) But this argument cannot be taken seriously given that plaintiffs themselves have delayed resolution of defendants’ 23(f)

⁵ To the extent plaintiffs are proposing that the parties work up one trial and then engage in the same exercise for a series of separate trials, such a proposal would ultimately result in improper claim-splitting unless the Court tries single-state classes in isolation because each subclass for each claim implicates a different set of state laws. (*See* Defs.’ Mem. at 12.) Although plaintiffs contend that Rule 42(b)—which governs the severance of claims—authorizes such separate trials (Pls.’ Opp’n at 15), their proposal would create yet another (more fundamental) problem by inviting different juries to decide cross-cutting issues such as causation, reliance and injury differently in multiple trials involving overlapping class members. *See In re Rhone-Poulenc Rorer Inc.*, 51 F.3d 1293, 1303 (7th Cir. 1995) (“The plan of the district judge in this case is inconsistent with the principle that the findings of one jury are not to be reexamined by a second, or third, or *n*th jury.”).

petitions by seeking and obtaining a two-week extension of time to file their opposition briefs. In any event, a short delay does not constitute material prejudice or harm to plaintiffs, particularly where, as here, “time is [not] of the essence” in obtaining the relief plaintiffs seek. *Brown*, 2012 WL 5818300, at *4. Plaintiffs argue that defendants’ cases are distinguishable because the stays at issue were entered after the appellate courts had decided to accept the petitions and after the parties had completed plenary briefing, meaning that the stays “would only result in a minor additional delay in prosecution.” (Pls.’ Opp’n at 17.) But it makes no difference whether the stay is sought before or after the petition is granted or appellate briefing has been completed because “Rule 23(f) appeals are expected to be resolved quickly, so that any delay in the[] proceedings would be relatively brief.” *Gray v. Golden Gate Nat’l Recreational Area*, No. C 08-00722 EDL, 2011 WL 6934433, at *3 (N.D. Cal. Dec. 29, 2011); *see also Brown*, 2012 WL 5818300, at *4 (granting stay prior to acceptance of 23(f) appeal); Fed. R. Civ. P. 23 advisory committee’s notes to 1998 amendment (“It is expected that the courts of appeals will act quickly in making the preliminary determination whether to permit appeal.”).

Relying on *Baker v. Sorin Group Deutschland GmbH*, No. 1:16-cv-00260, 2018 WL 8188426, at *3 (M.D. Pa. Jan. 2, 2018), plaintiffs also claim that a stay “would be particularly harmful” because it would delay the medical monitoring

class members’ “access to medical monitoring.” (Pls.’ Opp’n at 17-18.) However, in *Baker*, both the CDC and various hospitals had already sent out “notices that suggest[ed] that all patients exposed” to the product “receive medical monitoring,” 2017 U.S. Dist. LEXIS 235430, at *32; *see also Baker*, 2018 WL 8188426, at *3. Here, by contrast, no public health agency has recommended screening for VCD users, and at least one agency has actually discouraged it. *See* European Medicines Agency, *Lessons Learnt From Presence of N-Nitrosamine Impurities in Sartan Medicines*, 9 (June 23, 2020), https://www.ema.europa.eu/en/documents/report/lessons-learnt-presence-n-nitrosamine-impurities-sartan-medicines_en.pdf. Further, the notion that class members need medical monitoring as soon as possible is belied by the FDA’s pronouncement that any cancer risk posed by exposure to NDMA in VCDs would be, at most, a theoretical risk of 1 in 8,000, at the highest dose, for the entire period of time the medications were being sold. (*See* Defs.’ Mem. at 16 n.1.) Plaintiffs’ only response to such a de minimis risk is their assertion in a footnote that “*even one* cancer diagnosis is one too many.” (Pls.’ Opp’n at 18 n.5), effectively proving defendants’ point that their proposed medical-monitoring regime—which itself is highly invasive and risky—is not a one-size-fits-all proposition, as required for class certification.

IV. A STAY WOULD BE IN THE PUBLIC INTEREST.

Plaintiffs’ various arguments that a stay would not be in the public interest largely recycle their claim that defendants have not provided “good grounds” for appealing the class certification ruling (Pls.’ Opp’n at 19; *see also id.* at 20), which misperceives the public-interest prong and is not true for the reasons previously discussed. Although plaintiffs also argue that “the public has a strong interest in resolving this five-year-old litigation” (Pls.’ Opp’n at 19), “the public interest really is rooted in the *proper* resolution of the important issues raised in th[e] case,” *In re Lorazepam*, 208 F.R.D. at 6. And although plaintiffs also contend that “freeing up judicial resources is not a good basis to stay a case” (Pls.’ Opp’n at 20), defendants’ point is that the public “has an interest in the efficient use of judicial resources” and “prevent[ion] [of] potentially wasteful work on the part of the court and the parties,” *Brown*, 2012 WL 5818300, at *5. Accordingly, plaintiffs’ public-interest arguments lack merit and should be rejected.

CONCLUSION

For the foregoing reasons, as well as those set forth in defendants’ opening brief and 23(f) petitions, the Court should stay all remaining class-related deadlines and proceedings until the Third Circuit resolves the petitions and (if it grants them) rules on the merits of the appeal.

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on March 22, 2023, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system, which will send a notice of electronic filing to all CM/ECF participants in this matter.

/s/ Jessica Davidson

Jessica Davidson (DC Bar No. 457021)
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